UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,382	06/15/2001	Wan S. Lee	1408.017	8310

23405 7590 01/06/2005

HESLIN ROTHENBERG FARLEY & MESITI PC
5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,382	LEE ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, filed 11/01/2004.

Claims 1-15 and 18 are included in the prosecution.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment of the claims to recite "organic solvent" and "one phase" introduced a new matter to the scope of the claims because these limitations are is not described in the specification as originally filed.

3. Claims 1-15 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "ethyl acetate" as a solvent for the acrylic adhesive, does not reasonably provide enablement for the all the "organic solvents" as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is composition and method of its preparation, wherein the composition comprising acrylic adhesive having polyethylene oxide side chain dissolved in ethyl acetate, and a drug.

The breadth of the claims: The claims are broad. The claims encompass a wide class of organic solvents that not described in the specification. The examples used only ethyl acetate as a solvent for the acrylic adhesive.

The state of the prior art: The state of the art recognized the use of organic solvents to prepare composition for transdermal drug delivery; however, the art does not recognize the ethyl acetate to dissolve the acrylic adhesive before adding the drug.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on organic solvent other than ethyl acetate in the preparation of composition suitable for transdermal drug delivery. It is not obvious from the disclosure of ethyl acetate as a solvent for the acrylic adhesive if the other solvents will work. *In re Dreshfield,* 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article *"Broader than the Disclosure in Chemical Cases,"* 31 J.P.O.S. 5, by *Samuel S. Levin* covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to dissolving the acrylic adhesive in organic solvents other than ethyl acetate makes practicing the claimed invention unpredictable in the terms of using any organic solvent.

The presence or absence of working examples: The specification discloses only ethyl acetate as a solvent for the acrylic adhesive. No working examples to show using any other organic solvents. Therefore, the specification has enabled ethyl acetate and not other solvents.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant composition for transdermal drug delivery and method of its making without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

The following rejection were discussed in details in the previous office action and are maintained for reasons of record:

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,779,632 ('632).

US '632 disclosed a pressure sensitive adhesive used for transdermal pharmaceutical delivery devices comprising polyethylene oxide acrylates, disclosed by applicant in page 7, lines 1-2 as an adhesive having polyethylene oxide side chain, and any therapeutic active agent useful in transdermal delivery devices or salts of those drugs (abstract; col.10, lines 35-41; col.31, line 34; col.32, line 1). The pressure sensitive adhesive further comprising a solvent and a penetration enhancer that included oleic acid and isopropyl myristate (col.32, lines 7-20). The reference disclosed method for preparing a drug delivery device using the general method of mixing a solution of the drug and the adhesive, and coating the resulting adhesive composition on a backing (col.32, lines 17-26).

The limitations of claims 1, 2, and 18 are met by US '632 reference.

6. Claims 1, 4, 5, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,150,459 ('459).

US '459 discloses a polymer composition suitable for controlled release drug delivery devices and wound healing devices, said composition comprises acrylic backbone and poly(ethylene oxide) side chain (abstract; col.3, lines 52-54, 61-64; col.8, lines 56-67; col.9, lines 10-120; col.16, lines 45-49). The preferred molecular weight of the side-chain is above 200 and below 2000 and is present in amount of 20-60% of the polymer composition (col.3, lines 57-59; col.4, lines 14-23; col.9, lines 25-30; col.10, lines 53-61). The composition comprises active agent, and solvent and prepared by casting a solution comprising the polymer into a surface (col.12, lines 54-60).

The limitations of claims 1, 4, 5, and 18 are met by the reference.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '632 or US '459 in view of US 5,865,792 ('792).

The teachings of US '632 and US '459 are discussed above.

However, US '632 and US '459 do not teach the particular salts of the drugs as claimed in claims 6 and 13, the particular solvents of claims 7, or the amount of the drug, solvent and the penetration enhancer.

US '792 teaches a device for transdermal drug delivery comprising polymeric reservoir comprising anti-inflammatory agent, solvent and penetration enhancer (abstract; col.10, line 15). The preferred anti-inflammatory agent that eliminates tissue irritation is hydrocortisone succinate (col.2, lines 50-52; col. 3, lines 13-15). The solvent includes ethanol, isopropanol, glycols such as polyethylene glycol and polypropylene glycol, and sorbitan fatty acid esters that disclosed by applicants as penetration enhancer (col.7, lines 24-33). The polymer includes polyethylene oxide blended with polyacylic acid (col.9, lines 22-31).

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the drug, the solvent, and the penetration enhancer instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymer composition comprising acrylic backbone and poly(ethylene oxide) side chain as disclosed by any of US '632 and US '459 and select one of the suitable solvents and drug salts disclosed by US '792 to be included in the composition, motivated by the teaching of US '792 that the drug salt and particularly hydrocortisone succinate is the preferred anti-inflammatory drug that

eliminates tissue irritation, with reasonable expectation of having polymer composition comprising acrylic backbone and poly(ethylene oxide) side chain to deliver hydrocortisone succinate with success to the patient in need.

Response to Arguments

10. Applicant's arguments filed 11/01/2004 have been fully considered but they are not persuasive.

Absence of support for the amendment from the specification necessitated the maintenance of the art rejections.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600